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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,538	08/17/2001	Steve J. D. Bell	37070/205236	5069

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,538

Applicant(s)

BELL ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-15-02 and 2-6-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 11 and 12 have been renumbered 10 and 11 respectively.

Election/Restrictions

Applicant's election with traverse of Group II in the paper filed on 12-19-2003 is acknowledged. The traversal is on the ground(s) that the examination of the entire application will not impose a serious burden on the Examiner. A search of the claimed calcium phosphate particles would include methods of making said particles. This is not found persuasive because the searches of the various groups would not be coextensive in scope and therefore constitute a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 are pending. Claims 1-4 and 8-11 have been withdrawn from consideration.

Claims 5-7 are currently under examination.

Specification

The disclosure is objected to because of the following informalities: The specification fails to describe Figure 8.

Appropriate correction is required.

Claim Objections

Claims 5-7 are objected to because of the following informalities: Said claims are dependent on non-elected claims (inventions). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rendered vague and indefinite by the use of the phrase "induce immunity in a patient". It is unclear what is meant by said phrase. What immunological responses are encompassed by said term? Is Applicant referring to the induction of protective immunity or merely a given immunological response? The specification discloses the use of a myriad of pharmacologically active agents

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1645

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Relyveld (U.S.

Patent 4,016,252 – IDS- 4/15/02).

The instant claims are drawn methods of inducing immunity in a patient utilizing calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm coated with a pharmacologically active agent. Said particles are used in a vaccine composition comprising said particles and a pharmaceutically acceptable carrier and other excipient wherein said particles are delivered to a mucosal surface.

Relyveld discloses an aqueous gel of calcium phosphate useful for the preparation of adsorbed vaccines, prepared by contacting an antigen with an aqueous gel and their use as vaccines (i.e. induce immunity). Relyveld discloses the use of an inactivated polio virus as the “antigen” thereby targeting the resulting particles for mucosal (oral) delivery (see example 8). Moreover, Relyveld discloses the use of a sodium chloride solution as an excipient (see column 3, lines 65-68). With regard to particle size, Relyveld discloses that his gel “exhibits a marked colloidal character”. It is well known in the art that colloid is defined as a substance consisting of very tiny particles that are usually between 1 nm and 1000 nm in diameter and that are suspended in a continuous medium, such as a liquid, a solid or a gaseous substance. Therefore, Relyveld anticipates all the limitations of the claimed invention.

Art Unit: 1645

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RITA MIRAFLO
PRIMARY EXAMINER
3/30/04

Robert A. Zeman
March 29, 2004